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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

PAM PIEPER, individually and on behalf of all others similarly situated, Plaintiff, v. UNITEDHEALTH GROUP INCORPORATED, UNITEDHEALTHCARE, INC., UNITEDHEALTHCARE LIFE INSURANCE COMPANY, OPTUM, INC., and OPTUMRX, INC. Defendants.	Case No. **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

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Defined Terms in Plaintiff's Complaint

AASLD:	American Association for the Study of Liver Diseases
AMA:	American Medical Association
CFA:	Consumer Fraud Act Minn. Stat. § 325F.69, *et seq.*
CHC:	Chronic Hepatitis C
CHC Guidelines:	Guidelines established for the testing, management, and treatment of CHC by the American Association for the Study of Liver Diseases and Infectious Diseases Society of America.
Coverage Guidelines:	UnitedHealth's internal criteria for determining which CHC sufferers will be denied coverage for Harvoni treatment. *See* Exhibits B and C.
Covered expense:	An expense that is: A. Incurred while *you[]* or *your dependent's* insurance is in force under this *policy;* B. Covered by a specific

	benefit provision of this *policy*; and C. Not excluded anywhere in this *policy*. *See* Exhibit A at Page 24.
Covered person:	*[Y]ou, your* lawful *spouse* and each *eligible child:* A. Named in the application or enrollment form; or B. Whom *we* agree in writing to add as a *covered person.* *See* Exhibit A at Page 24.
DAA:	Direct-Acting Antiviral
FDA:	United States Food and Drug Administration
Finance Committee Report:	STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM (Comm. Print 2015), http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf (detailing the history behind the treatment of CHC)
Gilead:	Gilead Sciences, Inc. The company that distributes Harvoni.
IDSA:	Infectious Diseases Society of America
IOM:	Institute of Medicine
Medically necessary:	A health care service, supply, or drug provided for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, condition, disease, or its symptoms, that is determined by us or in consultation with an appropriate medical professional to be: A. In accordance with generally accepted standards of medical practice; B. Clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the covered person's illness, injury, condition, disease, or its symptoms; C. Not provided mainly for the covered person's convenience or that of the covered person's doctor or other health care provider; D. Not furnished solely to promote athletic achievement, a desired lifestyle, or to improve the

	covered person's environmental or personal comfort; and E. As cost effective as any established alternative service, supply, or drug that is as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the covered person's illness, injury, condition, disease, or its symptoms. *See* Exhibit A at Pages 27-28.
METAVIR Score:	METAVIR fibrosis score that classifies liver scarring from F0-F4.
PBM:	Pharmacy Benefits Manager
Pharmasset:	Pharmasset, Inc. The company that carried out the initial development and FDA approval of Harvoni.
Pieper UH Policy:	Ms. Pieper's United Health Policy—Policy Number 430 040 223
SVR:	Sustained Virologic Response
UDTPA:	Minnesota Deceptive Trade Practices Act Minn. Stat. § 325D.44, *et seq.*
UH Policies:	Health insurance programs, contracts, plans, and/or policies marketed and/or sold by UnitedHealth.

Plaintiff Pam Pieper ("Plaintiff"), individually and on behalf of all others similarly situated, alleges the following against Defendants UnitedHealth Group Incorporated ("UnitedHealth Group"), UnitedHealthCare, Inc. ("UnitedHealthCare"), and UnitedHealthcare Life Insurance Company ("UnitedHealthcare Life") (collectively, "UnitedHealth"), and Optum, Inc., and OptumRx, Inc. (collectively, "Defendants") based upon information and belief[1] except as to the allegations pertaining specifically as to Plaintiff that are based on personal knowledge.

I. INTRODUCTION

1. Plaintiff brings this class action lawsuit individually and on behalf of similarly situated Class members (defined below) against Defendants for their refusal to pay for Harvoni—a medically necessary treatment that can ***effectively cure*** Plaintiff's and Class members' chronic Hepatitis C ("CHC"). Defendants wrongfully denied coverage for Harvoni based on a desire to decrease costs and increase profits, in breach of the health insurance contracts Defendants entered into with Plaintiff and Class members and the implied covenant of good faith and fair dealing, and in violation of the Minnesota Uniform Deceptive Trade Practices Act Minn. Stat. § 325D.44, *et seq.* (the "UDTPA") and Consumer Fraud Act Minn. Stat. § 325F.69, *et seq.* (the "CFA").

2. UnitedHealth markets and/or sells health insurance programs, contracts, plans, and/or policies (the "UH Policies") to millions of people across the nation. *See, e.g.*, Exhibit A. Plaintiff and Class members purchased the UH Policies, entered into binding contracts with one or more Defendants, paid insurance premiums, and relied on Defendants to provide health

[1] Plaintiff's information and belief is based on an investigation (by and through counsel) which included, among other things, a review and analysis of publicly available information, news articles, reports to federal regulators, and additional analysis. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

insurance and prescription drug coverage under the terms set forth in the UH Policies and in good faith.

3. UnitedHealth Group's subsidiaries administer Plaintiff's and Class members' UH Policies and OptumRx, Inc. serves as the pharmacy benefits manager ("PBM") for the UH Policies. *See, e.g.*, Exhibit A. Defendants were required to exercise good faith and deal fairly with Plaintiff and Class members when making coverage decisions and/or administering the UH Policies.

4. The UH Policies are substantially similar in all material respects, are the complete agreement between Defendants and Plaintiff and Class members, and contain materially identical definitions of "Medically necessary" or definitions with immaterial differences with respect to the claims herein. Defendants' obligations to Plaintiff and the Class are identical. Plaintiff and Class members reasonably relied—as Defendants intended—on Defendants' express and implied representations in the UH Policies that they would provide health insurance and prescription drug coverage for Medically necessary treatments, and not unreasonably deny coverage in bad faith.

5. Plaintiff and Class members suffer from CHC, are "Covered persons" under the UH Policies, and Harvoni is a Medically necessary Covered expense for Plaintiff and Class members under the UH Policies. Plaintiff and Class members were prescribed Harvoni by their physicians to treat their CHC but were wrongfully denied coverage by Defendants. Rather than pay for the cost of Harvoni—a once daily tablet that can effectively cure CHC in eight to twelve weeks with minimal side effects—Defendants uniformly applied internal clinical guidelines (the "Coverage Guidelines"),[2] to wrongfully deny Harvoni coverage in breach of the implied and

[2] Exhibit B sets out UnitedHealth's Coverage Guidelines for 2015 and Exhibit C sets out UnitedHealth's Coverage Guidelines for 2014 (collectively, the "Coverage Guidelines").

express contractual obligations owed to Plaintiff and Class members and in breach of applicable state law, including the UDTPA and CFA.

6. Hepatitis C is a contagious blood-borne virus that attacks the liver and affects millions of people in the United States.[3] There is an acute form and a chronic form of Hepatitis C; CHC leads to an increase in mortality.[4] Approximately 75% to 85% of people who are infected with Hepatitis C are chronic carriers, and, until recent scientific breakthroughs, required extensive treatment of the chronic illness.[5] There are seven separate genotypes of the CHC virus; genotypes 1, 2, and 3 are the most prevalent in the United States.[6]

7. CHC can lead to a host of medical problems that shorten life expectancy.[7] For example, CHC patients are at an increased risk of developing advanced scarring of the liver—cirrhosis—which causes reduced liver function and is a life-threatening condition.[8] CHC patients are also at an increased risk of developing liver cancer, which has one of the highest mortality rates of any cancer.[9] Prior to experiencing irreversible liver damage, CHC sufferers may experience, among other things, a high risk of heart attack, fatigue, depression, arthritis, fever, itchy skin and jaundice.[10]

8. Before recent drug developments, individuals with CHC often underwent extensive treatment regimens lasting twenty-four or forty-eight weeks and consisting of daily

[3] Eric Chak, *et al.*, *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence*, 31 LIVER INT'L 1090, 1090-1101 (Sept. 2011), http://onlinelibrary.wiley.com/doi/10.1111/j.1478-3231.2011.02494.x/epdf.

[4] Stephen L. Chen and Timothy R. Morgan, *The Natural History of Hepatitis C Virus (HCV) Infection*, INT J MED SCI 2006, 47-52, http://www.medsci.org/v03p0047.htm.

[5] *See id.*

[6] Donald G. Murphy, *et al.*, *Hepatitis C Virus Genotype 7, a New Genotype Originating from Central Africa*, 53 J. CLINICAL MICROBIOLOGY 967, 967–72 (Mar. 2015), http://www.ncbi.nlm.nih.gov/pubmed/25520447.

[7] *See* Chen and Morgan, *supra* at n.4.

[8] *See id.*

[9] *See id.*

[10] *See id.*

pills and a weekly injection of a drug known as Interferon.[11] Interferon causes debilitating side effects; the worst of which can be flu like symptoms lasting throughout the twenty-four or forty-eight week treatment-regimens.[12] Interferon-treated CHC patients suffer the drug's side effects without any assurance that their Hepatitis C will be cured.[13] Interferon as a standalone drug has a poor SVR rate and, even in combination with antiviral drugs, the SVR rate is less than 50%.[14]

9. Within the last five years, pharmaceutical companies have developed direct-acting antiviral ("DAA") drugs for the treatment of CHC that significantly shorten the length of treatment, significantly reduce the side effects, and significantly increase the SVR rate.[15] These new DAA drugs do not require the use of Interferon to treat CHC, meaning that patients on DAA drugs do not have to suffer debilitating side effects.[16] Most importantly, the new DAA drugs are capable of ***curing*** CHC after only an eight to twelve week regimen of a once daily tablet. One of these new DAA drugs, Harvoni (ledipasvir-sofosbuvir), developed and distributed by Gilead Sciences, Inc. ("Gilead"), is at the heart of this class action lawsuit.

10. The United States Food and Drug Administration (the "FDA") approved Harvoni exclusively for the treatment of genotype 1 CHC patients in October of 2014, calling it a "breakthrough" drug.[17] Harvoni is the first drug approved for the treatment of CHC that does not

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[11] *See* STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM (Comm. Print 2015), 8, http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf (detailing the history behind the treatment of CHC) (hereinafter "Finance Committee Report").

[12] *See id.*

[13] *See id.* A patient is considered cured of Hepatitis C when a blood test is incapable of detecting the virus twelve or twenty-four weeks after treatment (depending on the treatment) based on the patient's sustained virologic response ("SVR") rate.

[14] *See id.*

[15] *See id.*

[16] *See id.*

[17] *See id.*

require combination with other drugs, and can effectively cure CHC in 94% to 100% of cases with little to no side effects.[18]

11. Notwithstanding the life-saving treatment offered by Harvoni, Defendants have limited the Class's access to this miracle drug by developing arbitrary coverage criteria requiring advanced liver scarring for CHC sufferers. *See* Exhibits B and C. Liver scarring severity is classified by the METAVIR fibrosis score ("METAVIR Score"), which is measured on a scale of F0 to F4.[19] METAVIR Scores between F0 and F2 represent no liver scarring to light liver scarring whereas METAVIR Scores between F3 and F4 represent severe liver scarring, with F4 representing cirrhosis.[20] Defendants' Coverage Guidelines cover Harvoni treatment only for patients who have a METAVIR Score of F3 or F4, or its equivalent. *See* Exhibit B at 1 (detailing Defendants' Coverage Guidelines for covering the payment of Harvoni). Advanced fibrosis and cirrhosis—as measured by a METAVIR Score of F3 and F4, respectively—can progress to end-stage liver disease and liver failure.[21]

12. The Coverage Guidelines are not a part of the UH Policies and are not in accordance with standard medical practice. Defendants have unlawfully applied the Coverage Guidelines to arbitrarily refuse Harvoni coverage for CHC patients who do not have a

[18] Shara Yurkiewicz, *Harvoni Safe and Effective for Cirrhotic Patients*, MEDPAGE TODAY, May 18, 2015, http://www.medpagetoday.com/MeetingCoverage/DDW/51605?xid=nl_mpt_DHE_2015-05-19&eun=g605133d0r (summarizing a study that demonstrated the effective cure rate of Harvoni).

[19] Thierry Poynard, *et al.*, *Fibrosis in Patients with Hepatitis C: Detection and Significance: Detection and Significance*, SEMINARS IN LIVER DISEASE, 2000, http://www.medscape.com/viewarticle/410846_2.

[20] *See id.*

[21] *See Cirrhosis*, PUBMED HEALTH, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022024/.

METAVIR Score of F3 or F4, or its equivalent,[22] in breach of the UH Policies and Defendants' duty of good faith and fair dealing, and in violation of state law, including the UDTPA and CFA.

13. Defendants' Coverage Guidelines also deviate from the standard of care in the medical community for the treatment of CHC. Since the development of new DAA drugs to treat CHC, such as Harvoni, the standard of care in the medical community has been to treat CHC as soon as the disease is diagnosed so that patients do not suffer the life-threatening complications associated with fibrosis and cirrhosis. Accordingly, as early as January 2014, the American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA") have jointly recommended that ***all*** CHC patients be treated with DAA therapies, regardless of disease progression. These recommendations were made in guidelines established for the testing, management, and treatment of CHC ("CHC Guidelines").[23] The CHC Guidelines expressly state that: "[t]reatment is recommended for ***all*** patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy."[24]

14. Plaintiff and Class members were diagnosed with CHC, prescribed Harvoni by their physicians, and unlawfully denied coverage. As a result, Plaintiff and Class members have been and continue to be irreparably damaged by Defendants' unlawful denial of coverage for Medically necessary Harvoni treatment.

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[22] Defendants' METAVIR Score requirement is the major determining factor of whether a patient will receive coverage for Harvoni treatment. While there are other tests that classify liver scarring, the METAVIR Score is the most common.

[23] *See* AASLD and IDSA, *When and In Whom to Initiate HCV Therapy, Recommendations for Testing, Managing, and Treating Hepatitis C,* http://www.hcvguidelines.org/printpdf/91.

[24] *AASLD and IDSA, When and In Whom to Initiate HCV Therapy, Recommendations for When and in Whom to Initiate Treatment,* http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (emphasis added).

15. At the time Defendants created the Coverage Guidelines and denied Plaintiff and Class members Harvoni coverage, Defendants knew or should have known that the standard of care for the treatment of CHC was treating the illness as soon as the patient was diagnosed.[25] Defendants' practice of denying coverage for Harvoni treatment for CHC sufferers without a METAVIR score of F3 or higher, or alternative scoring equivalent, is and was a deceptive trade practice in the course of Defendants' business. Further, Defendants are and were aware that their practice of denying Harvoni treatment based on the Coverage Guidelines creates a likelihood of confusion or misunderstanding in light of the terms of the UH Policies, including *inter alia*, the definition of Medically necessary.

16. Further, Defendants' wrongful denial of Harvoni coverage constitutes a "fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive trade practice" with the intent that Plaintiff and Class members would rely thereon in connection with Defendants' sale of the UH Policies and/or provision of health insurance and prescription drug coverage services in violation of the CFA.

17. As a result of Defendants' unlawful denial of Harvoni coverage in breach of the UH Policies and Defendants' duty of good faith and fair dealing, and in violation of the CFA, Plaintiff and Class members are entitled to actual damages in the amount of the retail cost of Harvoni and damages to be determined at trial. Plaintiff and Class members are also entitled to injunctive relief under the UDTPA and CFA.

[25] *See id.* ("[e]evidence clearly supports treatment in ***all*** BACK-infected persons . . . .") (emphasis added).

II. PARTIES

18. Plaintiff Pam Pieper is and was, at all relevant times, a citizen of the State of Texas residing in Hillsboro, Texas. On November 19, 2014, Plaintiff purchased a UnitedHealth Group health benefit plan on the individual market. *See* Exhibit A.

19. Plaintiff was prescribed Harvoni by her treating physician and denied coverage by Defendants.

20. Plaintiff's policy with UnitedHealth was in force at the time coverage for her physician-prescribed treatment with Harvoni was denied by Defendants.

21. OptumRx is the PBM under Plaintiff's policy.

22. Defendant UnitedHealth Group is a Delaware corporation with its principal place of business located at 9900 Bren Road East Minnetonka, Minnesota. UnitedHealth Group is the ultimate parent of the subsidiaries identified below.

23. UnitedHealthCare is a Delaware corporation with its principal place of business located at 9900 Bren Road East Minnetonka, Minnesota. UnitedHealthCare is one of two principal subsidiaries of UnitedHealth Group. UnitedHealthCare is registered to do business in Minnesota. Its registered office is located at 100 South 5th Street number 1075, Minneapolis, Minnesota.

24. UnitedHealthcare Life is a Wisconsin corporation with its principal place of business located at 3100 Ams Blvd, Green Bay, Wisconsin. UnitedHealthcare Life is a subsidiary of UnitedHealth Group. UnitedHealthcare Life is the underwriter of Plaintiff's health insurance plan.

25. Optum, Inc. is a Delaware corporation with its principal place of business located at 2300 Main Street, Irvine, California. Optum, Inc. is one of UnitedHealth Group's two main

subsidiaries. Optum, Inc. manages the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRX, Inc. (collectively, "Optum").

26. OptumRx, Inc. ("OptumRx") is a Delaware corporation with its principal place of business located at 2300 Main Street, Irvine, California. OptumRx is a subsidiary of UnitedHealth Group and serves as the PBM for the UH Policies. OptumRx is registered to do business in Minnesota and its registered office is located at 100 South 5th Street number 1075, Minneapolis, Minnesota.

27. Optum acts as an agent of UnitedHealth in its role as PBM under the UH Policies. UnitedHealth has the ability to control and exercises control over Optum, and Optum assents to UnitedHealth's control. UnitedHealth directs Optum to apply the Coverage Guidelines to deny coverage for Harvoni treatment for CHC sufferers without a METAVIR Score of F3 or F4, or its equivalent, and Optum relied on the Coverage Guidelines to deny prescription drug coverage for Harvoni for Plaintiff and Class members.

III. JURISDICTION AND VENUE

28. This Court has subject matter jurisdiction over all claims in this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because this lawsuit has been brought as a class action on behalf of a proposed class in excess of 100 members, the aggregate claims of the Class members exceed $5 million exclusive of interest and costs, and one or more of the members of the Class is a citizen of a different state than one or more Defendants.

29. This Court has personal jurisdiction over UnitedHealth Group because UnitedHealth Group's principal place of business is in the State of Minnesota and it regularly conducts business in the State of Minnesota, has sufficient minimum contacts with Minnesota, and avails itself of the laws of Minnesota.

30. This Court has personal jurisdiction over UnitedHealthCare because UnitedHealthCare's principal place of business is in the State of Minnesota and it regularly conducts business in the State of Minnesota, has sufficient minimum contacts with Minnesota, and much of the relevant conduct occurred in Minnesota.

31. This Court has personal jurisdiction over UnitedHealthcare Life because it is registered to do business in the State of Minnesota, regularly conducts business in the State of Minnesota, has sufficient minimum contacts with Minnesota, and much of the relevant conduct occurred in Minnesota.

32. This Court has personal jurisdiction over Optum, Inc. because it is registered to do business in the State of Minnesota, regularly conducts business in the State of Minnesota, has sufficient minimum contacts with Minnesota, and much of the relevant conduct occurred in Minnesota.

33. This Court has personal jurisdiction over OptumRx because it is registered to do business in the State of Minnesota, regularly conducts business in the State of Minnesota, has sufficient minimum contacts with Minnesota, and much of the relevant conduct occurred in Minnesota.

34. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the unlawful conduct alleged in this Complaint occurred in, was directed to, and/or emanated from this District, and because UnitedHealth Group is registered to conduct business in this District and maintains its principal places of business in this District.

IV. FACTUAL ALLEGATIONS

A. Chronic Hepatitis C ("CHC")

35. The Hepatitis C virus is small virus that is enveloped in Ribonucleic acid ("RNA"). The genetic sequence of the virus was first discovered in 1989. The Hepatitis C virus has a highly variable genome and is classified into multiple genotypes and sub-genotypes. There are seven different genotypes of the Hepatitis C virus and each genotype has its own sub-genotypes. There is no single drug that can treat the full spectrum of Hepatitis C virus genotypes and sub-genotypes. Instead, the FDA has approved drug regimens for specific Hepatitis C genotypes and sub-genotypes.

36. As described above, CHC can lead to a host of medical problems, including increased mortality. About 70% of CHC cases in the United States are of genotype 1, and the majority of these cases are of sub-genotypes 1a and 1b. It is estimated that genotypes 2 and 3 account for 16% and 12% of cases in the United States, respectively. Genotypes 4, 5 and 6 account for fewer than 4% of cases in the United States.[26] Genotype 1 is the most difficult to treat.

37. CHC results in inflammation, scarring, and cirrhosis of the liver and increases the risk of liver cancer.[27] If left untreated, CHC can cause serious illnesses, including cirrhosis, which can only be alleviated through a liver transplant.[28] Approximately 20% of CHC carriers

[26] *See, e.g.*, Jane P. Messina et al., *Global Distribution and Prevalence of Hepatitis C Virus Genotypes*, 61 Hepatology 77, 77–87 (2015); M. Michele Manos et al., *Distribution of Hepatitis C Virus Genotypes in a Diverse U.S. Integrated Health Care Population*, 84 J. Med. Virology 1744, 1744–1750 (2012), http://www.ncbi.nlm.nih.gov/pubmed/22997077.

[27] Liver cancer has one of the highest mortality rates of any cancer. The relative 5-year survival rate from liver cancer is about 15%. *See Learn About Cancer, Liver Cancer*, AMERICAN CANCER SOCIETY, http://www.cancer.org/acs/groups/cid/documents/webcontent/003114-pdf.pdf .

[28] *See* Finance Committee Report, *supra* n.11, at 7.

develop cirrhosis, and of those with cirrhosis, up to 20% develop liver cancer.[29] Cirrhosis is extensive scarring of the liver that degrades liver function and is a life-threatening condition. CHC patients can suffer other health issues including a higher risk of heart attack, fatigue, joint pain, depression, sore muscles, arthritis, and jaundice.[30] CHC is the leading cause of liver transplants in the United States.[31]

38. No vaccines have been developed to prevent CHC infection. Infection prevention and treatment are the sole options for dealing with CHC. The goal of CHC treatment is to reduce the patient's viral load. Thus, the effectiveness of any Hepatitis C drug is measured by the reduction in the viral count. A patient is considered cured of Hepatitis C when a blood test, twelve or twenty-four weeks after treatment, is incapable of detecting the virus. Being cured is referred to as showing an SVR.

39. Since the discovery of the existence of CHC, Interferon has been the primary treatment option. Interferon is a naturally occurring protein that cells secrete when they are attacked by a virus. Treatment with Interferon has many drawbacks; Interferon treatment requires injections and causes side effects, including flu-like symptoms such as fever, fatigue, muscle aches, and myalgia. Many patients report suffering flu-like symptoms during the entire course of Interferon treatment, which can last up to a year. The SVR (or cure) rate for Interferon is low—6% for twenty-four week and 16% forty-eight week regimens.

40. In 1998, the FDA approved the use of Ribavirin, an anti-viral drug, for use in combination with Interferon to treat CHC. The Interferon and Ribavirin combination improved the SVR rate for patients but continued to leave millions of patients uncured. The SVR (or cure)

[29] *See id.*

[30] *See* Chen and Morgan, *supra* n.4.

[31] *See id.*

rate for the Interferon and Ribavirin combination treatment is 34% for twenty-four week and 42% for forty-eight week regimens.

41. After the development of Ribavirin, the next advance was the development of DAA drugs, which work by attacking specific viral proteins within the Hepatitis C virus's RNA. In 2011, the FDA approved two DAAs, boceprevir (brand name Victrelis) and telaprevir (brand name Incivek). In 2013, the FDA approved two additional DAA's, simprevir (brand name Olysio) and Sovaldi. The new DAA drugs represented the first time that Hepatitis C patients could be treated with drugs that did not require use of Interferon and the corresponding negative side effects.

42. The FDA approved the use of Sovaldi without the use of Interferon for the treatment of genotype 2 and genotype 3 CHC patients. The larger group of CHC sufferers—genotype 1 CHC patients—still required the use of Interferon and ribavirin with Sovaldi. However, in October 2014, the FDA approved Harvoni—the first genotype 1 CHC treatment that did not require the use of Interferon.

B. Harvoni

43. Gilead, a Delaware company headquartered in Foster City, California, is a biopharmaceutical company that discovers, develops, and commercializes drugs in areas of unmet medical need. Gilead introduced Sovaldi and Harvoni to the market as effective cures for CHC.

44. Gilead acquired Sovaldi and Harvoni when it purchased Pharmasset, Inc. ("Pharmasset"), a pharmaceutical company based out of Princeton, New Jersey. Pharmasset carried out the initial development of the drugs and the process of FDA approval. Before Pharmasset could bring the drugs to the market, Gilead acquired Pharmasset in January 2012.

45. The FDA granted breakthrough therapy designation to Sovaldi on October 10, 2013.[32] Approximately two months later, on December 6, 2013, the FDA approved Sovaldi as a component of a combination antiviral treatment regimen for the treatment of CHC patients with genotypes 1, 2, and 3.[33] In November 2013, Gilead set the price of a standard twelve-week course of Sovaldi treatment at $84,000.[34] Almost a year later, on October 10, 2014, the FDA approved Harvoni for the treatment of genotype 1 CHC patients.[35] Gilead priced the standard twelve-week course of Harvoni treatment at $94,500.[36]

46. Today, for patients with genotype 1 CHC, the recommended treatment by the AASLD and IDSA is Harvoni.[37] According to the website HCV Advocate, which compiles data from clinical studies of Harvoni, the duration of Harvoni treatment depends on the patient's viral count and whether the patient has undergone previous CHC treatment. An eight-week regimen is used for treatment-naïve patients without cirrhosis and with a viral count of less than 6 million per milliliter of blood. A twelve-week regimen is used for treatment-naïve patients with or without cirrhosis and for treatment-experienced patients without cirrhosis. For treatment-experienced patients with cirrhosis, the treatment duration is twenty-four weeks. The recommended dosage is one tablet of Harvoni once daily, which contains 90 mg of ledipasvir and 400 mg of sofosbuvir. The reported SVR rate for Harvoni is 90% or above for all treatment durations, measured twelve weeks post-treatment.

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[32] FDA breakthrough therapy designation speeds up the process for a drug to be introduced to the market. *See Food and Drug Administration Safety and Innovation Act (DASIA), Fact Sheet: Breakthrough Therapies*, U.S. Food and Drug Administration, http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/DASIA/ucm329491.html.

[33] *See* Finance Committee Report, *supra* n.11, at 28.

[34] *See id.* at 62.

[35] *See id.* at 28.

[36] *See id.* at 61-62.

[37] *Initial Treatment of HCV Infection*, AASLD & IDSA, http://www.hcvguidelines.org/full-report/initial-treatment-have-infection.

C. Early Treatment of CHC Is the Standard of Care in the Medical Community

47. On January 29, 2014, the AASLD and the IDSA published the CHC Guidelines for Hepatitis C. The CHC Guidelines, entitled "*HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*," provide recommendations for the testing, management, and treatment of Hepatitis C.[38]

48. Since January 2014, the AASLD and IDSA have recommended the early treatment of Hepatitis C as the standard of care—meaning treatment should begin as soon as the patient is diagnosed with CHC. On October 22, 2015, the AASLD and IDSA updated their guidelines, stating that no impediments exist to the treatment of CHC patients who do not have advanced liver scarring, including patients who have a METAVIR Score of F0 or F1.[39] While the AASLD and IDSA had previously prioritized CHC treatment for patients with more advanced liver scarring, that decision was based on outdated logistical impediments—the associations never took the position that the treatment of CHC patients who do not have advanced liver scarring was not medically necessary.[40]

49. In support of the recommendation of the early treatment of Hepatitis C, the CHC Guidelines cite to studies that demonstrate that CHC patients who are treated at the early stages of their liver disease have statistically significant lower mortality rates.[41] These studies demonstrate that patients cured of CHC at an early stage live longer and healthier lives.[42]

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[38] The CHC Guidelines are available at hcvguidelines.org.

[39] *See* Home, WHEN AND IN WHOM TO INITIATE HCV THERAPY, AASLD and IDSA, http://www.hcvguidelines.org/full-report/when-and-whom-initiate-have-therapy.

[40] *See id.*

[41] *See id.* (citing, *e.g.*, Morgan, *et al.*, *Eradication of hepatitis C virus infection and the development of hepatocellular carcinoma: a meta-analysis of observational studies*, ANN INTERN MED, 2013 (documenting that among CHC sufferers, becoming virus free is associated with a more than 70% reduction in the risk of liver cancer and a 90% reduction in the risk of liver-related mortality and liver transplantation)).

[42] *See id.* (citing to numerous clinical studies that show that curing CHC early leads to "dramatic reductions in all-cause mortality").

D. Harvoni Is Medically Necessary under the Terms of Plaintiff's and Class Members' UH Policies

50. On information and belief, the UH Policies at issue are materially identical for Plaintiff and Class members and the operative terms summarized herein are included in each of the UH Policies sold to Plaintiff and Class members. Pursuant to the UH Policies, one or more Defendants agreed to provide payment for Medically necessary Covered expenses. *See* Exhibit A at Page 24, Page 27-28.

51. Treatment with Harvoni meets the definition of a Medically necessary Covered expense under the terms of the UH Policies and Defendants' refusal to cover Harvoni based on the Coverage Guidelines violates the terms of the UH Policies, Defendants' implied duty of good faith and fair dealing, and the UDTPA and CFA.

52. Under the UH Policies, the person named in the enrollment form is the Covered person. *Id*. at Page 24.

53. A Covered expense is an expense that is: "A. Incurred while *you[]* or *your dependent's* insurance is in force under this *policy;* B. Covered by a specific benefit provision of this *policy*; and C. Not excluded anywhere in this *policy*." *Id.*

54. With regard to prescription drug coverage, the UH Policies state that Covered expenses will include any drug prescribed to treat a chronic, disabling, or life threatening illness if:

> A. The drug has been approved by the United States Food and Drug Administration (USFDA) for at least one indication;
>
> B. The drug is recognized for treatment of the indication for which the drug is prescribed in:
>
> 1. The American Hospital Formulary Service Drug Information;

2. The United States Pharmacopoeia Drug Information; or

3. Substantially accepted peer-reviewed medical literature.

Exhibit A at Page 41.

55. The UH Policies also inform enrollees that Covered expenses will not include:

A. Experimental drugs that are not otherwise approved for an indication by the USFDA;

B. Drugs prescribed for treatment of a disease or condition that is excluded from coverage under the plan;

C. ***Any drug found to be not medically necessary for the treatment of the current disease, condition or syndrome,*** so long as the finding is not based on the fact that the drug is being prescribed for an off-label use; or

D. A drug that the USFDA has determined to be contraindicated for treatment of the current indication.

Id. (emphasis added)

56. Harvoni meets the requirements for a Covered expense as it is approved by the FDA to treat CHC and, *inter alia*, is recognized for the treatment of CHC in "[s]ubstantially accepted peer-reviewed medical literature."

57. Harvoni also does not meet any of the exclusions for Covered expenses in the UH Policies as it has not been found "to be not medically necessary for the treatment" of CHC. Rather, treatment of CHC with Harvoni is Medically necessary both under the UH Policies and the standard of care in the medical community.

58. Under the UH Policies, Medically necessary means:

> a health care service, supply, or drug provided for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, condition, disease, or its symptoms, that is determined by us or in consultation with an appropriate medical professional to be:

A. In accordance with generally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the covered person's illness, injury, condition, disease, or its symptoms;

C. Not provided mainly for the covered person's convenience or that of the covered person's doctor or other health care provider;

D. Not furnished solely to promote athletic achievement, a desired lifestyle, or to improve the covered person's environmental or personal comfort; and

E. As cost effective as any established alternative service, supply, or drug that is as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the covered person's illness, injury, condition, disease, or its symptoms.

Exhibit A at Page 27-28.

59. Further, Harvoni treatment for Plaintiff and the Class is in "accordance with generally accepted standards of medical practice" as defined in the UH Policies. *See id.* According to the UH Policies, "[g]enerally accepted standards of medical practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials." *See id.* at Page 26.

60. Thus, treatment of CHC with Harvoni meets the contractual definition of a Medically necessary Covered expense, and Defendants are contractually required to provide payment for Plaintiff's and Class members' Harvoni treatment.

61. Treatment of CHC with Harvoni for patients with a METAVIR Score of less than F3 is within the standards of acceptable medical practice in the United States. The American Medical Association ("AMA") defines medical necessity as:

> Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.[43]

62. The AMA further states that "[t]he 'prudent physician' standard of medical necessity ensures that physicians are able to use their expertise and exercise discretion, consistent with good medical care, in determining the medical necessity for care to be provided each individual patient."[44]

63. The Institute of Medicine ("IOM") has stated that: "[t]he criteria used for medically necessary services or services that conform to medical necessity are medical services that are (1) clinically appropriate for the individual patient, (2) based on the best scientific evidence, taking into account the available hierarchy of medical evidence, and (3) likely to produce incremental health benefits relative to the next best alternative that justify any added cost."[45] IOM noted that the "criteria are consistent with best practices and supported by legal precedent."[46]

64. Defendants have no basis to deny Harvoni treatment based on a requirement of advanced fibrosis because there is no lack of supply of Harvoni and the AASLD expressly states

[43] *Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits*, (Jan. 14, 2011), https://iom.nationalacademies.org/~/media/8D03963CA EB2445094 7C1AEC0CAECD85.ashx.

[44] *Id.*

[45] John K. Iglehart, *Defining Essential Health Benefits—The View from the IOM Committee*, N. Engl. J. Med. (Oct. 20, 2011), http://www.nejm.org/doi/full/10.1056/NEJMp1109982?viewType=Print.

[46] *Id.*

that health insurers should not "prioritize" treatment and recognizes the "need to treat ***all***" CHC patients.[47]

65. Thus, Harvoni meets all of the requirements of a Medically necessary treatment and Covered expense under the UH Policies and, there is nothing in the UH Policies or standard medical practice that requires CHC sufferers' medical conditions to deteriorate to severe fibrosis or cirrhosis in order for their treatment to be considered Medically necessary or to qualify as a Covered expense. Moreover, Defendants cannot cite to any standards of acceptable medical practice in the United States or contractual provision in the UH Policies that allows for artificial restrictions on treatment of CHC which require Plaintiff's and Class members' health to deteriorate to an irreversible and irreparable level before they can be treated and cured with Harvoni.

E. All Defendants Apply the Same Coverage Guidelines to Arbitrarily Deny Coverage for Harvoni Treatment

66. On information and belief, Defendants have developed, approved and uniformly applied the Coverage Guidelines that are used to make Harvoni coverage decisions across all of Defendants' entities that administer health insurance plans and/or prescription drug programs under the UH Policies.

67. Despite an established standard of care for treating all CHC sufferers, the Coverage Guidelines provide the following basis for their denial of Harvoni coverage for patients without advanced fibrosis: "[b]ased on current evidence-based guidance from professional specialty societies and physician subject matter experts, UnitedHealthcare will

[47] *AASLD Position on Treating Patients with Chronic Hepatitis C Virus*, http://www.aasld.org/aasld-position-treating-patients-chronichcv# sthash.7KlZ3Xqy.dpuf (emphasis added).

provide benefit coverage in cases of hepatitis C infection when there is documented evidence of stage 3 or stage 4 hepatic fibrosis." Exhibit C.

68. The Coverage Guidelines cite to the IDSA and AASLD prioritization of treatment with DAAs for those patients with advanced fibrosis (METAVIR F3) as a basis for the standards established in the guidelines. *See id.* However, as detailed herein, the IDSA and AASLD have recommended early treatment of CHC since January 2014 and never stated that the treatment of CHC patients who do not have advanced liver scarring was not medically necessary.

F. Defendants Unlawfully Deny Coverage for Harvoni Treatment

69. Defendants have applied and continue to apply the Coverage Guidelines to artificially restrict treatment of CHC patients and Harvoni to individuals with F3 or F4 stage liver fibrosis and unlawfully deny coverage to all other CHC sufferers—a practice that is inconsistent with and in breach of the express and implied obligations in Plaintiff's and Class members' UH Policies, and the UDTPA and CFA. Defendants apply these Coverage Guidelines as a cost-saving measure without regard to their contractual obligations or the health of the patient.

70. As a matter of law, Defendants are required to make coverage decisions based on the policy language in the UH Policies and in good faith. Despite the plain language of the UH Policies, Defendants did not apply the contract language to determine whether Harvoni prescribed by a physician was a Medically necessary Covered expense. Rather, as alleged herein, Defendants relied upon their internal Coverage Guidelines—which are not in Plaintiff's and Class members' contracts—to arbitrarily deny the Class coverage for treatment with Harvoni. This practice breaches the terms of the UH Policies and Defendants' duty of good faith and fair dealing and injures Plaintiff and Class members by denying them a potentially life-saving medication and cure for CHC.

71. Defendants' reliance on the Coverage Guidelines to wrongfully deny coverage for Harvoni treatment also violates the UDTPA and CFA.

72. Given Defendants' pattern and practice of uniformly applying the Coverage Guidelines to deny coverage for Harvoni treatment to all CHC sufferers without a METAVIR Score of F3 or F4, or its equivalent, any exhaustion of administrative remedies would be futile.

G. Class Representative Allegations

73. Effective January 1, 2015, Plaintiff Pam Pieper enrolled in one of the UH Policies—Policy Number 430 040 223 (the "Pieper UH Policy")—and paid a monthly premium of $794.99 in exchange for health insurance coverage from UnitedHealth. *See* Exhibit A at Page 12. Under the Pieper UH Policy, Ms. Pieper's prescription drug program is administered by OptumRX. *See* Exhibit A at Page 6; Exhibit D.

74. The Pieper UH Policy, consistent with all Class members' UH Policies, provides coverage for Medically necessary Covered expenses—the only coverage criteria disclosed to Plaintiff and Class members in the UH Policies.

75. Ms. Pieper has been diagnosed with and suffers from CHC. Ms. Pieper's treating physician, Dr. Adil Habib, prescribed Harvoni as the appropriate treatment and cure for Ms. Pieper's CHC. Dr. Habib is an American Board of Internal Medicine certified gastroenterologist and hepatologist at The Liver Institute at Methodist Dallas in Dallas, Texas.

76. On November 9, 2015, OptumRx, the PBM listed in Ms. Pieper's UH Policy, received a Harvoni prior authorization form from Ms. Pieper and Dr. Habib. *See* Exhibit H. The prior authorization form requires a prescribing doctor to provide a patient's medical information, including documentation of the "Member's HCV genotype," "Pre-treatment HCV RNA level," "HCV reinfection following liver transplantation," and whether the "Member has cirrhosis." Exhibit F.

77. On November 9, 2015, OptumRx sent Ms. Pieper a letter stating that OptumRx could not fill her prescription for Harvoni because they did not receive the information required to provide Harvoni to Ms. Pieper under the Coverage Guidelines. *See* Exhibit G. According to the letter, Ms. Pieper was required to "[s]ubmi[t] [] medical records documenting stage 3 hepatic fibrosis" using, among other things, a "[l]iver biopsy confirming a METAVIR score of F3, or alternative scoring equivalent." *Id.*

78. On November 10, 2015, OptumRx sent Ms. Pieper a letter identical to its November 9, 2015 letter. *Compare* Exhibit G *with* Exhibit H. That same day, UnitedHealth sent Ms. Pieper a letter denying coverage for Harvoni using nearly identical language—stating Harvoni is covered only in cases where liver scarring "has reached the equivalent of a stage 3 METAVIR score or higher." Exhibit D.

79. Thus, applying the Coverage Guidelines—rather than the terms of the UH Policies—Defendants arbitrarily determined that Ms. Pieper had not shown severe enough liver fibrosis to be treated with Harvoni and cured of CHC. *Compare* Exhibits B and C (setting out Coverage Guidelines) *with* Exhibit D (denying coverage).

80. Prior to December 14, 2015, Ms. Pieper's physician, Dr. Habib, appealed Defendants' November 10, 2015 denial of coverage for Harvoni. Dr. Habib sent Defendants all of the necessary information regarding Ms. Pieper's CHC diagnosis along with an appeal of the denial and another prescription for Harvoni treatment for Plaintiff. *See* Exhibit E.

81. On December 28, 2015, Defendants replied to Dr. Habib's appeal, informing Ms. Pieper that "no benefits are available" because she "does not meet the criteria." *Id.* Specifically, Defendants denied Ms. Pieper's appeal for Harvoni coverage and refused to fill her prescription because she did not show "stage 3 or 4 hepatic fibrosis" as evidenced by a "[l]iver biopsy

confirming a METAVIR score of F3 or F4, or alternative scoring equivalent. . . ." *Id.* Defendants' denial of Dr. Habib's appeal filed on behalf of Ms. Pieper was the final step in the administrative appeal process under the Pieper UH Policy.

82. As a result of Defendants' wrongful refusal to fill Ms. Pieper's Harvoni prescription, Ms. Pieper is not taking any medication to treat her CHC and has been wrongfully deprived of treatment for her CHC.

83. According to Defendants, "[u]nder current UHC Guidelines, which were developed after the review of the current peer reviewed medical literature, Harvoni is to be covered for the treatment of genotype 1 HCV [CHC] infection only if the patient meets certain-guideline requirements," including advanced fibrosis as indicated by a METAVIR Score of F3 or higher. *Id.*

84. Defendants' arbitrary requirement for CHC sufferers to experience severe fibrosis, indicated by a METAVIR Score of F3 or higher, or its equivalent, before providing coverage for Harvoni treatment violates Plaintiff's and Class members' right to receive Medically necessary treatment under the terms of the UH Policies, and places artificial restrictions on treatment that are not agreed upon or disclosed in the UH Policies and are not in accordance with the standard of care for the treatment of CHC in the medical community.

85. Defendants' pattern and practice of denying Harvoni coverage for patients without a METAVIR Score of F3 or higher, or its equivalent, without including that requirement in the UH Policies, is in breach of their contractual obligations, creates a likelihood of misunderstanding and confusion for Plaintiff and Class members in violation of the UDTPA, and constitutes a "fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive trade practice" in violation of the CFA.

V. CLASS ACTIONS ALLEGATIONS

86. Plaintiff brings this action pursuant to Federal Rule of Civil Procedure 23 on behalf of the following Class:

> All persons suffering from chronic Hepatitis C who are or were insured by UnitedHealth or its affiliates, subsidiaries, agents or related entities, and were (1) prescribed Harvoni by their treating physician; and (2) denied coverage for Harvoni because they did not have a METAVIR Score of F3 or F4, or its equivalent, by one or more Defendants or their affiliates, subsidiaries, agents or related entities (the "Class").

87. Excluded from the proposed Class are Defendants and their affiliates, subsidiaries, agents or related entities, directors, officers and/or employees. Any judicial officer assigned to this action is also excluded. Plaintiff reserves the right to revise the definition of the Class based upon subsequently discovered information.

88. This action is brought and may be properly maintained as a class action under Federal Rules of Civil Procedure 23(a) and 23(b)(1), 23(b)(2) and/or 23(b)(3).

89. The Class is so numerous that joinder of all members is impracticable. Plaintiff believes that there are at thousands of proposed Class members throughout the United States.

90. Common questions of law and fact exist as to all Class members and predominate over any issues solely affecting individual members of the Class. The common questions of law and fact include but are not limited to:

- whether any Defendant was contractually obligated to provide Plaintiff and Class members with coverage for Medically necessary treatment while the UH Policies were in force;
- whether the treatment of CHC with Harvoni is Medically necessary under the terms of the UH Policies;
- whether the treatment of CHC with Harvoni is a Covered expense under the terms of the UH Policies;
- whether Harvoni is the standard of care for treating CHC;

- whether any Defendant breached the UH Policies and/or Defendants' implied covenant of good faith and fair dealing by denying Plaintiff and Class members coverage for Harvoni while the UH Policies were in force;
- whether UnitedHealth Group and/or UnitedHealthCare violated the Minnesota Uniform Deceptive Trade Practices Act and/or Consumer Fraud Act by denying Plaintiff and Class members coverage for Harvoni; and
- whether Plaintiff and Class members are entitled to injunctive relief, specific performance and/or actual damages for Defendants' violations of contractual and/or statutory obligations.

91. Plaintiff's claims are typical of the claims of the Class. As alleged herein, Plaintiff and Class members sustained damages arising out of the same course of unlawful conduct by Defendants.

92. Plaintiff is willing and prepared to serve the Class in a representative capacity with all of the obligations and duties material thereto. Plaintiff will fairly and adequately protect the interests of the Class and has no interests adverse to, or which conflict with, the interests of the members.

93. Plaintiff's interests are co-extensive with, and not antagonistic to, those of the absent Class members. Plaintiff will undertake to represent and protect the interests of the absent Class members.

94. Plaintiff has engaged the services of the undersigned counsel. Counsel is experienced in complex litigation, will adequately prosecute this action, and will assert and protect the rights of, and otherwise represent, Plaintiff and the absent Class members.

95. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty to be encountered in the management of this litigation that would preclude its maintenance as a class action.

96. Class action status is warranted under Rule 23(b)(3) because questions of law or fact common to the members of the Class predominate over any questions affecting only

individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

97. The Class may also be certified under Rule 23(b)(1)(A) and (B) because the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants, would be dispositive of the interests of nonparties to the individual adjudications, and would substantially impair the ability of such nonparties to protect their interests.

98. The Class may also be certified under Rule 23(b)(2) because Defendants have acted on grounds generally applicable to the Class, thereby making it appropriate to award final injunctive relief or corresponding declaratory relief, including specific performance, with respect to the Class as a whole.

99. The interest of Class members in individually controlling the prosecution of separate actions is theoretical and not practical. The Class has a high degree of similarity and is cohesive. Plaintiff anticipates no difficulty in the management of this matter as a class action.

VI. CLAIMS

COUNT I
Breach of Contract
(Against All Defendants)

100. Plaintiff and Class members incorporate and re-allege each and every allegation set forth in the foregoing paragraphs as if fully set forth herein.

101. Plaintiff and Class members entered into the UH Policies with one or more Defendants, through which Plaintiff and Class members agreed to pay monthly premiums to one or more Defendants in exchange for Defendants' agreement to provide health insurance coverage and prescription drug coverage to Plaintiff and Class members.

102. Plaintiff and Class members performed their contractual obligations under the UH Policies by paying monthly premiums to one or more Defendants.

103. Defendants materially breached the terms of Plaintiff and Class members' UH Policies by, *inter alia*:

(a) failing to apply the appropriate standard for coverage when evaluating Plaintiff's and Class members' claims for coverage of Harvoni treatment, including the criteria for Medically necessary required by the UH Policies;

(b) arbitrarily applying the Coverage Guidelines to deny coverage for CHC sufferers without a METAVIR Score of F3 or F4, or its equivalent;

(c) failing to find that treatment with Harvoni is a Covered expense under Plaintiff's and Class members' UH Policies;

(d) denying coverage to Plaintiff and Class members for Harvoni treatment that is covered by the UH Policies; and

(e) requiring that Plaintiff's and Class members' health and medical condition deteriorate to F3 or F4 stage liver fibrosis, resulting in irreversible damage and irreparable harm, before providing treatment with Harvoni that is Medically necessary under the UH Policies.

104. On information and belief, Defendants have breached the terms and provisions of materially identical UH Policies sold to Plaintiff and Class members by applying the Coverage Guidelines to unlawfully deny coverage for Harvoni, and other presently unknown acts and omissions, which will be proven at trial.

105. As a direct and proximate result of Defendants' material breaches of their contractual obligations, Plaintiff and Class members have been wrongfully denied Harvoni coverage, have not received the benefit of their bargain, and have suffered and continue to suffer damages, including the retail cost of Harvoni treatment and other damages to be proven at trial.

106. Alternatively, Plaintiff and Class members are entitled to specific performance of Defendants' obligations under the UH Policies to provide Harvoni coverage because further

delay will cause irreversible and irreparable harm to the health of Plaintiff and Class members, for which monetary damages will not be an adequate remedy.

COUNT II
Breach of Implied Covenant of Good Faith and Fair Dealing
(In the Alternative Against All Defendants)

107. Plaintiff and Class members incorporate and re-allege each and every allegation set forth in the foregoing paragraphs as if fully set forth herein.

108. An implied covenant of good faith and fair dealing is included in every contract, including the UH Policies.

109. Defendants have a duty of good faith and fair dealing in their performance of the UH Policies. The implied covenant requires that Defendants exercise good faith towards Plaintiff and Class members when making coverage decisions and/or administering the UH Policies and requires Defendants comply with the spirit, not just the letter of the contracts.

110. By entering into a contractual relationship with Plaintiff and Class members, Defendants agreed to perform their obligations under the UH Policies in good faith and to deal fairly and not unreasonably deny health insurance and/or prescription drug coverage to Plaintiff and Class members.

111. Defendants breached the implied covenant of good faith and fair dealing in the UH Policies by, *inter alia*:

(a) unreasonably denying coverage for Plaintiff's and Class members' claims for Harvoni treatment;

(b) arbitrarily applying the Coverage Guidelines to deny coverage for CHC sufferers without a METAVIR Score of F3 or F4, or its equivalent;

(c) denying coverage to Plaintiff and Class members for Harvoni treatment in bad faith based on Defendants' desire to decrease costs and increase profits;

(d) unreasonably failing to give due consideration to Plaintiff's and Class members' health and welfare when considering claims for coverage of Harvoni treatment; and

(e) requiring that Plaintiff's and Class members' health and medical condition deteriorate to F3 or F4 stage liver fibrosis, resulting in irreversible damage and irreparable harm, before providing treatment with Harvoni which can effectively cure Plaintiff's and Class members' CHC.

112. As a direct and proximate result of Defendants' breaches of the implied covenant of good faith and fair dealing, Plaintiff and Class members have suffered and continue to suffer damages, including the retail cost of Harvoni treatment and other damages to be proven at trial.

113. Alternatively, Plaintiff and Class members are entitled to specific performance of Defendants' obligations under the UH Policies to provide Harvoni coverage because further delay will cause irreversible and irreparable harm to the health of Plaintiff and Class members, for which monetary damages will not be an adequate remedy.

COUNT III
Violation of Minnesota's Uniform Deceptive Trade Practices Act § 325D.44, *et seq.*
(Against UnitedHealth Group and UnitedHealthCare)

114. Plaintiff and Class members incorporate and re-allege each and every allegation set forth in the foregoing paragraphs as if fully set forth herein.

115. UnitedHealth Group and UnitedHealthCare are persons under Minn. Stat. § 325D.44, subd. 1.

116. Plaintiff and Class members are persons "likely to be damaged by a deceptive trade practice of another." Minn. Stat. § 325D.45.

117. UnitedHealth Group and UnitedHealthCare engaged in a "deceptive trade practice" "in the course of business, vocation, or occupation" by "engag[ing] in any [] conduct which similarly creates a likelihood of confusion or of misunderstanding." Minn. Stat. § 325D.44.

118. Plaintiff and Class members entered into valid health insurance contracts with one or more Defendants and paid premiums which entitled them to payment for Medically necessary Covered expenses including treatment with Harvoni.

119. UnitedHealth Group and UnitedHealthCare denied coverage for Harvoni as a way to artificially limit the number of CHC sufferers who would be given access to Harvoni in order to decrease costs and increase profits at the expense of Plaintiff and the Class.

120. Despite the clear terms of Plaintiff's and Class members' contracts (which do not arbitrarily restrict access to Harvoni), UnitedHealth Group and UnitedHealthCare require Plaintiff and Class members to deteriorate to F3 or F4 stage liver fibrosis before providing Harvoni treatment coverage—an irreparable harm.

121. UnitedHealth Group and UnitedHealthCare's conduct of arbitrarily denying Harvoni treatment coverage to CHC sufferers without F3 or F4 stage liver fibrosis, including Plaintiff and Class members, creates a likelihood of confusion or misunderstanding in violation of the UDTPA given the representations made in the UH Policies that health insurance and prescription drug coverage will be provided for Medically Necessary treatment. *See* Minn. Stat. § 325D.44.

122. UnitedHealth Group and UnitedHealthCare's pattern and practice of denying Harvoni coverage based on undisclosed Coverage Guidelines—not a part of the UH Policies—creates a likelihood of confusion or misunderstanding in violation of the UDTPA. *See* Minn. Stat. § 325D.44.

123. Plaintiff and Class members are "likely to be damaged by" UnitedHealth Group and UnitedHealthCare's "deceptive trade practice" as they are forced to continue to suffer from CHC without Harvoni—a treatment that can cure their chronic illness. Minn. Stat. § 325D.45.

124. As a proximate result of UnitedHealth Group and UnitedHealthCare's deceptive trade practice, including requiring that CHC patients suffer advanced fibrosis evidenced by a METAVIR Score of F3 or higher, Plaintiff and Class members will suffer irreversible and irreparable harm to their medical condition and health.

125. Because Plaintiff and Class members will suffer irreparable harm as a result of UnitedHealth Group and UnitedHealthCare's deceptive trade practice, Plaintiff and Class members are entitled to injunctive relief requiring UnitedHealth Group and UnitedHealthCare to abide by their contractual obligations in the UH Policies to provide coverage for Harvoni treatment for Plaintiff and Class members. Minn. Stat. § 325D.45.

126. Plaintiff and Class members are entitled to all costs of litigation and attorney's fees because, *inter alia*, UnitedHealth Group and UnitedHealthCare have "willfully" engaged in the deceptive trade practice alleged herein. Further, UnitedHealth Group and UnitedHealthCare engaged in the practice of denying Harvoni coverage to patients without advanced fibrosis with the knowledge that the trade practice was deceptive. Minn. Stat. § 325D.45.

COUNT IV
Violation of Minnesota's Consumer Fraud Act § 325F.69, *et seq*.
(Against UnitedHealth Group and UnitedHealthCare)

127. Plaintiff and Class members incorporate and re-allege each and every allegation set forth in the foregoing paragraphs as if fully set forth herein.

128. Pursuant to the Private Attorney General Act, Minn. Stat. § 8.31, subd. 3a, any person injured by a violation of the Minnesota Consumer Fraud Act § 325F.69 may bring a civil action. Minn. Stat. § 8.31, subd. 3a (2003).

129. Plaintiff and Class members are persons and consumers under the CFA. *See* Minn. Stat. § 325F.69.

130. UnitedHealth Group and UnitedHealthCare are persons under the CFA. *See* Minn. Stat. § 325F.69, subd. 1.

131. UnitedHealth Group and UnitedHealthCare marketed and sold the UH Policies with the intent that Plaintiff and Class members would rely on UnitedHealth Group and UnitedHealthCare to provide health insurance coverage. Plaintiff and Class members reasonably relied on UnitedHealth Group and UnitedHealthCare to provide health insurance coverage—pursuant to the terms of the UH Policies—in exchange for the monthly premiums paid by Plaintiff and Class members.

132. UnitedHealth Group and UnitedHealthCare's use of the Coverage Guidelines—rather than any contractual provision in the UH Policies—to deny Harvoni c overage to CHC sufferers without a METAVIR Score of F3 or higher, including Plaintiff and Class members, constitutes a "fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive trade practice" in violation of the CFA.

133. UnitedHealth Group and UnitedHealthCare employed a "fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive trade practice" with the intent that Plaintiff and Class members would rely thereon in connection with their sale of the UH Policies and their provision of health insurance and prescription drug coverage services in violation of the CFA.

134. As a direct and proximate result of UnitedHealth Group and UnitedHealthCare's wrongful denial of Harvoni coverage in violation of the CFA, Plaintiff and Class members have suffered and continue to suffer irreparable harm in the form of irreversible deterioration of their medical condition and health, and actual damages in the amount of the retail cost of Harvoni treatment and damages to be determined at trial.

135. As a result of UnitedHealth Group and UnitedHealthCare's wrongful denial of Harvoni coverage in violation of the CFA, Plaintiff and Class members are entitled to damages, costs of litigation, attorneys' fees, and other equitable relief. *See* Minn. Stat. § 8.31; Minn. Stat. § 325F.69.

136. The public interest will benefit from UnitedHealth Group and UnitedHealthCare being held liable for their CFA violations, including, inter alia, being required to provide Medically necessary treatment promised to be provided in the UH Policies. Minn. Stat. § 325F.69.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter a judgment against Defendants and in favor of Plaintiff and the Class, and award the following relief:

A. that this action be certified as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, declaring Plaintiff as the representative of the Class and Plaintiff's counsel as counsel for the Class;

B. award Plaintiff and Class members appropriate relief, including, *inter alia*, actual damages sustained by Plaintiff and the Class as the result of Defendants' material breach of the terms of the UH Policies;

C. order equitable, injunctive, and declaratory relief as may be appropriate, including specific performance of Defendants' contractual obligations under the UH Policies to provide coverage to Plaintiff and Class members for the Medically necessary Harvoni treatment;

D. award all costs of prosecuting the litigation, including expert fees and attorneys' fees under Minn. Stat. § 325D.45; Minn. Stat. § 8.31; Minn. Stat. § 325F.69; and other applicable laws;

E. award pre- and post-judgment interest; and

F. grant such additional relief as this Court may deem just and proper.

VIII. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

Dated: March 16, 2016

Respectfully submitted,

CHESTNUT CAMBRONNE

/s/ Karl L. Cambronne

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**Pro hac vice applications forthcoming*